

## **REMARKS**

The only issues outstanding in the Final Rejection of November 27, 2009, are the rejections under 35 U.S.C. 112 and 103. Reconsideration of these issues, in view of the following discussion, is respectfully requested.

### **Rejection Under 35 U.S.C. 112**

Claim 26 remains rejected under 35 U.S.C. 112, first paragraph. It is argued, at page 2 of the Office Action, that the “emulsifier-free emulsion is not clearly disclosed within the specification.” Applicants respectfully disagree with this assertion.

It appears that the 112 rejection is, perhaps, the “new” rejection characterized in the Office Action, inasmuch as the previous rejection under 35 U.S.C. 112 of this claim stated that the emulsifier-free emulsion was not clearly disclosed as it was “difficult to determine what an emulsifier is.” The Office Action now admits that emulsifiers are well understood in the art (see page 3 of the Office Action) but argues that “emulsifier-free emulsion” is indefinite. The Office Action further states, at page 3, that it is “unclear what emulsions composition [sic] lack the presence of an emulsifier.” However, it is respectfully, but extremely strongly, submitted that one of ordinary skill who is familiar with emulsions would have utterly no problem interpreting these terms. Chemists familiar with emulsions know well that it is possible to produce an emulsion without the use of emulsifiers. The formation of an emulsion depends on the interfacial tension between the two phases of the emulsion. An emulsifier can be used to reduce interfacial tension in order to facilitate the formation of the emulsion, or in order to stabilize the emulsion. However, such emulsifiers are not required, and it is well known that an emulsion produced without the aid of an emulsifier is an “emulsifier-free” emulsion. Thus, the present disclosure, disclosing a composition which may be an emulsion, e.g., a water in oil or oil in water emulsion, and further indicating that such emulsions are obtainable “in a conventional manner” (see page 54, lines 28-end, and see page 62, lines 16-27, and lines 29-31 disclosing that emulsions “may” comprise emulsifiers) clearly supports the common understanding of one of ordinary skill in the art which is that emulsifiers may optionally be used, but are not employed if

an emulsifier-free emulsion is to be produced. Thus, the term is clearly definite, well understood in the art, and the rejection under 35 U.S.C. 112 should be withdrawn. The same is respectfully requested.

### **Rejections Under 35 U.S.C. 103**

Claims 1, 10, 13-16 and 27 remain rejected under 35 U.S.C. 103 over Heger '166 taken with Harivel '238. Reconsideration of this rejection is again respectfully requested.

At page 6-9 of the Office Action, this rejection is repeated essentially as it appeared in the prior Office Action. The present Office Action does not comment on applicant's prior reply to this rejection. However, it is submitted that that prior reply clearly establishes the patentability of the present invention, over this misapplied combination of references. As the present Office Action does not comment on applicant's prior argument, it is submitted that simply repeating the rejection in the Final Rejection, is violative of MPEP §707.07(f), entitled "Answer All Material Traversed" which states that where the applicant traverses any rejection, "the Examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it." There has been no mention of this portion of the applicant's prior argument in the present Final Rejection.

It is moreover again submitted that the rejection does not render the present claims obvious. Heger, cited in the previous rejection, discloses aqueous dispersions of organic UV filters which are sparingly water-soluble or water-insoluble. The "UV filter substances" are a colloiddally disperse phase, which colloiddally disperse phase may exhibit a core/shell structure, where the core comprises the UV filter and the surrounding shell comprises a protective colloid ([0022]). Suitable polymers for this coating matrix are preferably water-soluble or water-swellaable, see paragraph [0025], disclosing gelatins such as Collagel A, *starch*, dextrin, or polymers based on neutral or ionic monomers such as ethylene oxide or lactic acid. Furthermore, in paragraph [0023] the purpose of this polymer shell is explained to be the stabilization of the particles in their colloidal state from heterogeneous particle growth. The office action argues that the shell of the particle can be silica, citing paragraph [0127]. However, this paragraph refers not to the shell coating of the particle but to part of the process used to produce a dry powder from

the light protection agent which has already been polymer-coated. See paragraph [0123]. Thus, the coating materials cited by the Examiner ([0127]) (e.g. silica) are not added until the process of spray or freeze drying (when the capsules already exist). This does not result in a capsule but rather in an amorphous silica structure. Furthermore, these coating agents favor the formation of agglomerates, whereas no single particles are obtained. Redispersion of the capsules (see paragraph [0129]) suggests that the capsules are released from the coating material. As a result, Heger does not teach silica as an encapsulating agent.

Instead, suitable organic polymers for the surrounding shell disclosed by Heger et al. (see above) differ strongly from inorganic silica. In addition, as described above, one of ordinary skill in the art would not have employed the coating agent cited in paragraph [0127] as a capsule matrix, instead using it to coat the previously encapsulated particles. In contrast to Heger et al., provides several advantages: The hydrophilicity of the walls of the capsules can be chosen irrespective of the solubility of the UV filter, the photostability of the filters is enhanced, the skin penetration and skin irritation of the UV filters can be suppressed and problems concerning the preparation (resulting from interactions between the components) can be avoided (see the present application at paragraphs [0011] – [0015]). Furthermore, capsules are known to be sensitive to mechanical and strong thermal stress, which may result in the encapsulation breaking open and in release of the substances included therein. However, the present application enables structural conservation of the encapsulation, which is of great importance since the contact with the skin is to be avoided. It is not obvious that the structure of the capsules would be conserved during the process of spray- or freeze-drying and a person skilled in the art would not have considered encapsulating the UV filters which are to be obtained by spray- or freeze-drying. Without some indication that a silica coating would survive. Such indication, and thus motivation, is absent.

Similarly, the combination with Harivel would not have motivated one of ordinary skill in the art to encapsulate UV filters which are to be obtained by spray- or freeze-drying according to the present invention. Harivel does nothing to remedy the deficiencies of the primary reference. Harivel discloses foamable aqueous UV filter compositions such as sunscreens, which may be encapsulated. See page 11, lines 33-34. The capsule walls of such a formulation may preferably be made of silica (see page 12, lines 10-11) but Harivel fails to disclose spray or freeze-drying of

the compositions in their preparation. One of ordinary skill in the art would not have found it obvious to spray or freeze-dry the compositions of Harivel, for example in the process of Heger, since the expectation would have been that the fragile silica would have been damaged.

Moreover, any suggestion of the obviousness of such combination is clearly rebutted by the advantages of the materials of the present invention. The indication in Heger that encapsulation of the UV filters stabilizes their colloidal state does not suggest to one of ordinary skill in the art that the present materials would possess the non-obvious advantage of easy ability of selection of the hydrophilicity of capsule walls, a respective of the solubility of the UV filter, and increased photostability of the filters, with skin penetration and skin irritation thereof being suppressed. Accordingly, it is submitted that this combination of references fails to suggest the presently claimed materials. It is thus submitted that this rejection should be withdrawn.

Claims 1, 2, 7-9, 17-20, 22 and 24-27 are rejected under 35 U.S.C. 103 over Harivel '238 taken with Heger '166. It is submitted that this rejection, which differs from that previously discussed only by the reversal of the order of the references cited, again must fail to suggest the present claims. As admitted at page 5 of the Office Action, Harivel does not teach that the encapsulated UV filters are in powder form obtained by spray drying or freeze drying. As noted previously, one of ordinary skill in the art would *not* have found it obvious to spread or freeze dry Harivel's compositions, because one of ordinary skill in the art would have expected that the fragile silica employed in Harivel would have been damaged by such harsh treatment. This issue, raised previously, remains unaddressed in the Final Rejection, but it is submitted that consideration thereof clearly mandates the failure to adapt the process in the manner argued in the Office Action. Accordingly, this rejection must also be withdrawn.

Finally, claim 21 is once again rejected under 35 U.S.C. 103 over Heger, Harivel and Herzog. Again, applicant's prior discussion of this rejection has not been treated in the Final Rejection. As Herzog is cited solely for its disclosure of a self-tanning agent, and does not remedy the deficiencies of the above-noted references, it is clear that this rejection also must fail. Withdrawal thereof is again respectfully requested.

Finally, claim 23 remains rejected under 35 U.S.C. 103 over Heger, Harivel and Chaudhuri. As with the prior rejections noted above, this rejection was also made previously and

applicant's discussion thereof has not been treated in the Final Rejection. Chaudhuri is cited solely for its teaching of a photostabilizer, and does nothing to remedy the above-noted deficiencies of Heger and Harivel. This rejection must also fail.

The claims of the application are clearly in condition for allowance. However, if the Examiner has any questions or comments, she is invited to telephone the undersigned at the number below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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